

OCT 20 2000

K001646



2200 Faraday Avenue
Carlsbad, CA 92008
(760) 603-5300
Fax (760) 603-5901

510(k) Summary of Safety and Effectiveness

Company Information: Puritan-Bennett Corporation
A subsidiary of Mallinckrodt Inc.
2200 Faraday Avenue
Carlsbad, CA. 92008

Contact Information: Mary Funk
Senior Regulatory Affairs Specialist
Phone Number: (760) 603-5957
Fax Number: (760) 603-5907

Date Summary Prepared: May 25th 2000

Product Name: 840 Ventilator with NeoMode Option

Common Name: Ventilator

Classification: Class II
Continuous Ventilator (per 21 CFR 868.5895)

Predicate Devices: Puritan-Bennett Corporation, a subsidiary of
Mallinckrodt Inc., is claiming substantial equivalence to
the following:

- Siemens Servo 300 Ventilator
- Neoflow option for the Dräger Evita 4 Ventilator

Device Description:

The 840 NeoMode Option is a software modification to the 840 Ventilator System that expands the population range of the 840 Ventilator to include neonatal patients. The 840 NeoMode option is available as an integrated part of the 840 Ventilator or as a separate software upgrade kit. A neonatal expiratory filter, designed to accommodate the lower flow rates and the smaller volume targeted breaths, is available as part of this accessory kit. The NeoMode Option expands the current 840 ventilator settings to include those required for the mechanical ventilation of neonatal patients with ideal body weights as low as 0.5 kg, tidal volumes as low as 5 ml and a respiratory system compliance as low as 0.25 ml/cmH₂O.

With the exception of some ventilator and alarm settings that are modified to accommodate the NeoMode Option, the basic functionality of the 840 Ventilator System remains the same.

Device Description (cont'd):

When used for neonatal applications, the 840 Ventilator supports the following ventilation modes and breath types:

Ventilation Modes:

- Assist/control (A/C).
- Spontaneous (SPONT).
- Synchronous Intermittent Mandatory Ventilation (SIMV).
- BiLevel mode.

Breath Types:

- Volume-Controlled (VC). Available in A/C and SIMV.
- Pressure-Controlled (PC). Available in A/C and SIMV.
- Pressure Support (PS). Available in SIMV and SPONT.

Intended Use:

The intended use of the 840 Ventilator with NeoMode Option is to provide continuous ventilation to patients requiring respiratory support. This product is intended to cover a variety of clinical conditions.

The intended patient population range includes adults, pediatrics, infants and neonates with ideal body weights (IBW) as low as 0.5 kg.

The 840 Ventilator with NeoMode Option is intended for use in hospitals and hospital-type facilities that provide respiratory care for patients requiring respiratory support. It may be used during hospital and hospital-type facility transport provided that electrical power and compressed gas are supplied.

The 840 Ventilator with NeoMode Option is not intended to be used in the presence of flammable anesthetics.

It is a prescription use device that is intended for sale by or on the order of a physician.

Technological Characteristics:

The 840 Ventilator with NeoMode Option is substantially equivalent to the predicate devices, the Servo 300 Ventilator manufactured by Siemens and the Neoflow option for the Evita 4 Ventilator manufactured by Dräger. All three ventilators share the same technological characteristics. They are all microprocessor-controlled (Servo 300 is analog/microprocessor based) and are designed to offer the same modes of ventilation and breath types to the same patient populations within similar environments of use. The design of the pneumatics systems are comparable in that they are all electrically powered. Both the 840 and the Dräger Evita 4 Ventilators utilize active exhalation valves.

Technological Characteristics (cont'd):

The alarm designs are similar although the 840 Ventilator with NeoMode Option incorporates a hierarchical structure that distinguishes between high, medium and low urgency alarms. The safety systems on the 840 Ventilator with NeoMode Option are equivalent to those on the predicate devices – the same tests, background checks, emergency modes and safety valves are standard options. All three ventilators can be used with an optional compressor; battery back-up is also standard equipment.

The 840 Ventilator contains a Digital Communications Interface (DCI) which incorporates an RS-232 serial port thus enabling the 840 Ventilator to communicate with external devices such as monitors, computers or information systems. The 840 Ventilator with NeoMode Option, the Servo 300 and the Dräger Evita 4 with Neoflow option all have nurse call remote capabilities.

The same general principles were applied to all designs and they incorporate similar technologies, materials, components, features and energy sources.

Determination of Substantial Equivalence:

The primary function of the 840 Ventilator with NeoMode Option, the Siemens Servo 300 and the Dräger Evita 4 with Neoflow option is to mechanically ventilate patients (neonates, infants, pediatrics and adults) who require respiratory support. The technological characteristics of the three products are the same and raise no new questions of safety and effectiveness. This is further supported by the test data that was generated on the 840 Ventilator with NeoMode Option which demonstrates all the product requirements and performance characteristics are within specifications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 20 2000

Ms. Mary E. Funk
Puritan-Bennett Corporation
2200 Faraday Avenue
Carlsbad, CA 92008-7208

Re: K001646
Puritan-Bennett 840 Ventilator System with NeoMode Option
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: August 23, 2000
Received: August 24, 2000

Dear Ms. Funk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

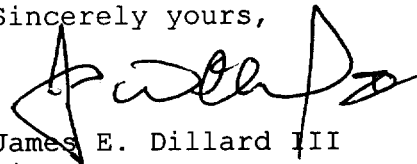
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name.

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.7 INDICATIONS FOR USE STATEMENT

Applicant: Puritan-Bennett Corporation (a subsidiary of Mallinckrodt Inc.)

510(k) Number: K001646

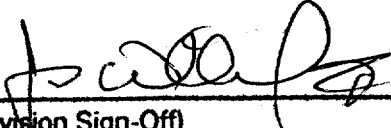
Device Name: 840 Ventilator with NeoMode Option

Indications for use: The 840 Ventilator with NeoMode Option provides continuous ventilation to patients requiring respiratory support. The NeoMode Option, which is used on neonatal patients with Ideal Body Weights (IBW) as low as 0.5 kg, is intended to cover a variety of clinical conditions. The 840 Ventilator with NeoMode Option is intended for use in hospitals and hospital-type facilities. It may be used during hospital and hospital-type facility transport provided that electrical power and compressed gas are supplied.

Prescription Use: Yes (Per 21 CFR 801.109)

~~PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED~~

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)
(Optional Format 1-2-96)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001646

Prescription Use X

or

OTC Use _____